In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 29, 2018

SUSAN DEAN,	*	PUBLISHED
Petitioner,	*	No. 16-1245V
v.	*	Chief Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal Decision; "Received"; "Vaccine"; "Administration of a Vaccine"; Prick Percutaneous Allergy Test.
Respondent.	*	

Ronald C. Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Mallori B. Openchowski, U.S. Department of Justice, Washington, DC, for respondent.

DECISION DISMISSING CASE[1]

On September 30, 2016, Susan Dean ("petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she "suffered a significant aggravation" of an unidentified "underlying respiratory condition" as a result of an influenza ("flu") vaccine prick percutaneous allergy test performed on October 7, 2013. Petition at Introduction & ¶ 2; Petitioner's Response to Respondent's October 30, 2017 Motion to Dismiss, filed November 27, 2017 ("Pet. Resp.") at Introduction (ECF No. 34).

[1] This decision will be posted on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole decision will be available to the public in its current form. Id.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act" or "the Act").

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner has not met her legal burden. Petitioner has failed to demonstrate that she "received a vaccine as set forth in the Vaccine Injury Table."[3] 42 U.S.C. § 300aa-11(c)(1)(A). Accordingly, petitioner is not entitled to compensation and her petition is dismissed.

I. BACKGROUND

A. Procedural History

Petitioner filed her claim on September 30, 2016, and she filed the first medical records on October 4 and 20, 2016. See Petitioner's Exhibits ("Pet. Exs.") 1-18. An initial status conference was held on October 27, 2016, during which the undersigned discussed the records that had been filed at that point and ordered petitioner to file additional medical records and a Statement of Completion. Petitioner filed the additional records, and on January 26, 2017, respondent filed a status report indicating that he was not amenable to settlement discussions. Status Report dated January 26, 2017 (ECF No. 19).

Respondent thereafter filed a Rule 4(c) Report recommending against compensation. Respondent's Report ("Resp. Rept.") (ECF No. 21). Respondent raised the issue of whether petitioner had received a vaccine under 42 U.S.C. § 300aa-11(c)(1)(A), arguing that the prick percutaneous allergy test petitioner underwent did not constitute receipt of a vaccine as intended by the statute. Resp. Rept. at 17. Respondent further argued that even if the allergy test were considered a vaccine under the Act, petitioner had not met her burden of proving by preponderant evidence that she experienced a significant aggravation of an underlying illness as set forth in Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009). Resp. Rept. at 17-19.

During a status conference held on April 6, 2017, the parties and the undersigned agreed that this case presents an issue of first impression with regard to whether petitioner's percutaneous allergy test constitutes receipt of a vaccine under the Act. Order dated April 6, 2017 (ECF No. 23). The parties were ordered to file briefs detailing their respective positions, which the undersigned reviewed during a status conference held on September 21, 2017. Id. Respondent argued in his brief that petitioner's claim "lacks the threshold factual and legal basis to establish entitlement to compensation [and] must be dismissed." Respondent's Response to the Court's April 6, 2017 Order ("Resp. Resp. to April 6, 2017 Order") at Conclusion (ECF No. 28). The undersigned accordingly requested that respondent file a motion to dismiss the case. During the status conference, the parties and the undersigned also discussed the definition of a prick percutaneous allergy test and the parties were ordered to file a joint stipulation as to the definition accompanied by supporting evidence.

On October 30, 2017, the parties filed their Joint Stipulation Regarding Definition of Prick Percutaneous Allergy Test ("Joint Stip. dated Oct. 30, 2017"), wherein the parties stipulated that the agreed-upon definition of prick percutaneous allergy test is "a small amount of

[3] The Vaccine Injury Table is located at 42 C.F.R. § 100.3.

an allergen placed or pricked on the epidermal layer of the skin." Joint Stip. dated Oct. 30, 2017, at ¶ 2 (ECF No. 32). In support of their joint definition, the parties also filed information regarding testing and procedures for percutaneous prick tests from the American College of Allergy, Asthma, and Immunology ("ACAAI"), the Mayo Clinic, and the Asthma and Allergy Foundation of America ("AAFA"). See Joint Stip. dated Oct. 30, 2017, at Tab A.

Respondent also filed a Motion to Dismiss on October 30, 2017. Mot. to Dismiss (ECF No. 33). Respondent argued that a prick percutaneous allergy test does not provide immunization and therefore is not a "vaccine" as intended by the statute. Id. at 5-6. Respondent further argued that to include a diagnostic allergy test as a vaccine set forth in the Vaccine Act would be to "expand the scope of Vaccine Act coverage beyond the clear meaning of its terms." Id. at 6.

Petitioner filed a response to respondent's Motion to Dismiss on November 27, 2017. Petitioner's Response to Respondent's October 30, 2017 Motion to Dismiss ("Pet. Resp.") (ECF No. 34). Petitioner argued that she received a vaccine under the Act because the content of the allergy test was the flu vaccine itself, which is a vaccine listed on the Table. Id. at 3.

The allergy test at issue notably did not include a full dose of flu vaccine; rather, it contained two "test doses." Joint Stip. dated Oct. 30, 2017, at ¶ 4. On January 23, 2018, the undersigned ordered the parties to file a joint stipulation as to the definition of "test dose" as used in the allergy test. The undersigned also requested information regarding the usual concentration of flu vaccine when administered intramuscularly as compared with that of a test dose, as well as any protocols normally used regarding the concentration and amount of flu vaccine used in the allergist's office where the test was administered. Petitioner filed the additional information on February 23, 2018, and on March 4, 2018, the parties filed a joint stipulation as to the definition of "test dose." Joint Stipulation and Status Report, filed March 4, 2018 ("Joint Stip. and Status Report") (ECF No. 42). The parties stipulated that "there is not a uniform standard governing the quantity of allergen administered in a skin prick allergy test or a uniform definition of the term 'test dose.'" Joint Stip. and Status Report at ¶ 3.

On April 20, 2018, the undersigned requested additional information regarding Fluzone, the flu vaccine used in petitioner's prick percutaneous allergy test, and on March 4, 2018, petitioner filed the document Highlights of Prescribing Information from Fluzone manufacturer Sanofi Pasteur. Pet. Ex. 23.

This matter is now ripe for adjudication on respondent's Motion to Dismiss.

B. Summary of Relevant Facts

In order to reach this decision, the undersigned fully reviewed the entire record. This section is a summary of the facts deemed most relevant to the present limited issue: as a threshold matter, whether petitioner may recover compensation under the Vaccine Act for any alleged injury sustained due to a prick percutaneous allergy test for the flu vaccine.

1. Petitioner's Medical History Prior To Allergy Test

Petitioner was born on July 3, 1960. Pet. Ex. 1 at 1. Prior to the allergy test at issue, petitioner reported a history of childhood asthma, "horrible bronchitis frequently," and exercise-induced asthma. Pet. Ex. 4 at 35. Petitioner had a documented history of "asthma, with status asthmaticus" as an adult.[4] Pet. Ex. 2 at 85, 90, 99, 102, 109. According to the earliest medical records available, on April 4, 2011, petitioner presented to Dr. Leo Gibson, her primary care physician, with complaints of cough and shortness of breath. Pet. Ex. 2 at 141-42. Dr. Gibson diagnosed petitioner with an upper respiratory infection and asthma for which he prescribed antibiotics and an Albuterol inhaler. Id.

On May 25, 2011, petitioner saw a pulmonologist, Dr. Robby Keith, for evaluation and management of her asthma. Pet Ex. 4 at 35-38. Dr. Keith noted "significant comorbid conditions of obstructive lung disease" and dyspnea that worsened with exertion and alleviated with rest.[5] Id. at 35. Dr. Keith prescribed oral prednisone and a Symbicort inhaler. Id. at 38. On June 22, 2011, petitioner returned to Dr. Keith and noted that she was breathing much better. Id. at 48. Petitioner stated that she did not like using the Symbicort inhaler but wanted to continue it because "her breathing [was] so much better." Id. Petitioner returned to Dr. Keith on October 11, 2011, complaining of moderate cough, increased shortness of breath, and chest pain related to a recent upper respiratory infection that had persisted for two weeks. Id. at 55-57. Petitioner was again assessed with dyspnea and asthma. Id.

Petitioner returned to Dr. Keith for a routine follow-up on February 28, 2012, and he again noted petitioner's "significant comorbid conditions of restrictive lung disease" and advised her to continue using her inhaler. Pet. Ex. 4 at 59-61. The following month, on March 20, 2012, petitioner called Dr. Keith to report another upper respiratory infection with accompanying shortness of breath and cough, for which he prescribed prednisone over the phone. Id. at 62-63. Petitioner returned for a follow-up appointment with Dr. Keith on August 28, 2012, during which he weaned petitioner off her Symbicort inhaler but advised that she continue to use an Albuterol inhaler as needed. Id. at 66-68.

Petitioner called Dr. Keith's office on October 12, 2012, complaining of symptoms related to another upper respiratory infection, including wheezing and shortness of breath; she was again prescribed prednisone over the phone. Pet. Ex. 4 at 70. Petitioner reported that she took prednisone three times over the winter for treatment of her asthma. Pet. Ex. 13 at 1. Petitioner did not return again to Dr. Keith for management of her symptoms until after the allergy test at issue.

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[4] Status asthmaticus is "a particularly severe episode of asthma that does not respond adequately to ordinary therapeutic measures and may require hospitalization." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1767 (32d ed. 2012) [hereinafter "DORLAND'S"].

[5] Dyspnea is "breathlessness or shortness of breath; difficult or labored respiration." DORLAND'S at 582.

2. Petitioner's Allergy Test

Petitioner was a 53-year-old operating room nurse when the allergy test at issue was administered on October 7, 2013. Pet. Ex. 2 at 1-2. During petitioner's long career at Thomas Memorial Hospital in South Charleston, West Virginia, she had been exempt from receiving the annual flu vaccination required of all employees because she had experienced "a reaction to a flu vaccine years ago." Petitioner's Affidavit ("Pet. Aff.") at ¶ 2 (Pet. Ex. 16). To remain exempt, petitioner would provide a letter from Dr. Gibson stating that she "should not be administered a [f]lu [v]accine due to severe allergies," and she was required instead to wear a facemask during the flu season.[6] Id.; Pet. Ex. 2 at 108. In 2013, the hospital's policy changed and petitioner was required to demonstrate her allergy to the flu vaccine through medical testing in order to remain exempt. Pet. Aff. at ¶ 2.

On October 7, 2013, petitioner presented to Thrush & Clark Allergists for allergy testing to the flu vaccine. Pet. Ex. 13 at 1. On the day of her visit, upon review of systems, it was documented that petitioner presented with nasal congestion, itching and watery eyes, runny nose, sneezing, joint and muscle pain, and anxiety.[7] Pet. Ex. 13 at 2. It was also noted that she had been in a car accident recently. Id.

Petitioner described the reaction to her flu shot ten years prior at that visit: she had experienced a "slight local reaction" and "wheezing within 1 hour" of the shot. Pet. Ex. 13 at 1.[8] Additionally, petitioner stated that she began to feel sick within 24 hours and sought treatment from Dr. Gibson three days post-vaccination. Id. Petitioner stated that she "was in bed for three weeks" with "febrile, classic pneumonia" that "exacerbated her asthma." Id. She further reported that Dr. Gibson treated her with Biaxin and penicillin and thereafter provided her letters to remain exempt from the hospital's annual flu shot requirement. Id.

The facts surrounding the allergy testing performed on October 7, 2013, are not in dispute. The parties stipulated that the prick percutaneous allergy test was performed using "two test doses of the influenza virus vaccine." Joint Stip. dated Oct. 30, 2017, at ¶ 4. The parties further stipulated to a definition of "prick percutaneous allergy test" as "a small amount of an allergen placed or pricked on the epidermal layer of the skin." Id. at ¶ 2. While the parties were unable to stipulate as to a definition of "test dose" or a uniform standard governing the quantity of allergen administered in a prick percutaneous allergy test, they did file a letter from the nurse

[6] Dr. Gibson also routinely provided letters to petitioner's employer explaining that she suffered from chronic migraine headaches that were exacerbated by fatigue and requesting that she not be required to work midnight shifts. Pet. Ex. 2 at 83, 104, 150, 155, 161, 170, 184, 192-93.

[7] Review of Systems was documented by Lisa G. Burgess, RN, at 2:45 p.m., which appears to be prior to the testing procedure. Pet. Ex. 13 at 2.

[8] Petitioner's claim of a prior anaphylactic reaction to the flu vaccine is not documented in the record, but petitioner did submit a letter from Dr. Gibson to petitioner's employer dated October 12, 2012, which stated that she should not receive the flu vaccine due to "severe allergies." Pet. Ex. 2 at 108.

practitioner who performed petitioner's allergy test, Sandra J. Wotring, RN, MSN, describing the usual protocols used during flu vaccine allergy testing and the details of petitioner's specific allergy test. See Joint Stip. and Status Report at ¶ 3; Pet. Ex. 22. The letter was co-signed by L. Blair Thrush, M.D. Pet. Ex. 22 at 2.

The letter states as follows:

> Ms. Dean received two allergy prick/scratch tests to full strength Fluzone Influenza Virus Vaccine. The amount of the vaccine that she was exposed to with the prick testing would be extremely minute as there is no penetration of the epidermis as one would have with [i]ntradermal skin testing. She [d]id not receive [i]ntradermal testing because she tested mildly to moderately positive to the initial prick testing.
>
> If she would have received [i]ntradermal testing the dose given would have been 0.02 ml – 0.05 ml. One could extrapolate that the amount of exposure with the prick tests would be far less than that of [i]ntradermal testing. As you know, Ms. Dean only received the two prick skin tests. She did not receive [i]ntradermal tests nor did she receive the actual [f]lu vaccine of 0.5 ml [i]ntramuscularly.
>
> The protocol for [i]nfluenza skin testing involves prick testing a full strength concentration along with a negative control and a positive [h]istamine control. If the results of this testing are negative with adequate controls, the patient then receives full strength [i]ntradermal testing along with [i]ntradermal negative control and positive [h]istamine control.

Pet. Ex. 22 at 2.

After testing, petitioner was noted to have had no reaction to the negative control, a local reaction to the histamine, and a reaction to each of the two test doses of flu vaccine. Pet. Ex. 1 at 4; Pet. Ex. 13 at 4. After the initial prick testing, Nurse Wotring advised petitioner to "avoid flu vaccine due to positive skin tests and wheezing after last flu vaccine." Pet. Ex. 13 at 2. Petitioner was given a note to take to her employer so that she would not be administered a flu shot. Id.; Pet. Ex. 1 at 5.

Petitioner alleges that immediately after the testing, her arm became red and swollen, she began to feel itchy, her throat felt scratchy, and she began sneezing. Pet. Aff. at ¶ 4. Petitioner further stated that she was treated with Benadryl, cortisone cream, and oral prednisone. Id. Respondent correctly noted that neither petitioner's alleged reaction nor the resulting treatment is documented in the medical records. Resp. Rept. at 4.

3. Fluzone

The allergy test at issue was performed using two test doses of the flu vaccine Fluzone. Pet. Ex. 1 at 4; Pet. Ex. 22 at 1. Fluzone is "an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine." Highlights of Prescribing Information at 2. Fluzone is approved for

intramuscular use only. Id. at 1. The preferred site for intramuscular injection in patients older than 36 months is the deltoid muscle. Id. at 3. Fluzone should not be administered intravenously or subcutaneously. Id.

One full dose of Fluzone for injection in patients nine years and older (including adults) is 0.5 ml. Highlights of Prescribing Information at 1. As Nurse Wotring explained, if petitioner had received intramuscular testing, the dose of flu vaccine administered intramuscularly would have been between 0.02 ml – 0.05 ml, but "[o]ne could extrapolate that the amount of exposure with the prick tests would be far less." Pet. Ex. 22 at 1.

4. Prick Percutaneous Allergy Test

The parties stipulated that the definition of prick percutaneous allergy test is "a small amount of an allergen placed or pricked on the epidermal layer of the skin." Joint Stip. dated Oct. 30, 2017, at ¶ 2. The literature from the ACAAI filed in support of the definition provides that prick tests are "used by allergists as diagnostic aids." Id., Tab A at 1. In the skin prick test, "a diluted allergen is applied with a prick on the surface of the skin." Id. The area is observed to determine whether a reaction develops. A "wheal" indicates sensitivity to the allergen.[9] Id.

Here, the parties stipulated that petitioner's "allergy testing was positive for a flu vaccine allergy." Joint Stip. dated Oct. 30, 2017, at ¶ 4.

5. Petitioner's Post-Allergy Test Condition

Petitioner alleges that her symptoms worsened by October 9, 2013, when she began to feel congested and developed a cough. Pet. Aff. at ¶ 5. Petitioner stated that her coughing became more severe by the next day, October 10, 2013, and that she developed "stomach distress." Id. She called Dr. Gibson's office that day stating that she had a "[r]eaction to allergy testing," with complaints of head congestion, chest tightness, wheezing, productive cough with green septum, chills, and an elevated temperature. Pet. Ex. 20 at 2. Dr. Gibson prescribed antibiotics and cough medicine over the phone. Id.

By October 13, 2013, petitioner alleges that she was so extremely short of breath that she could not complete a sentence. Pet. Aff. at ¶ 6. Her fiancé, a doctor, became concerned and contacted the pulmonologist on call at Thomas Memorial Hospital, who admitted petitioner that day for acute exacerbation of her asthma. Id.; Pet. Ex. 11 at 1325. Petitioner was administered steroids, nebulizers, and antibiotics, which markedly improved her breathing by the time she was examined by Dr. Takubo, the pulmonologist. Pet. Ex. 11 at 1325. Upon exam, Dr. Takubo noted that petitioner was afebrile at 98.7 degrees and that she had some "mild expiratory wheezing, otherwise, [lungs are] mostly clear." Id. at 1326. He further noted that petitioner's chest x-ray was unremarkable. Id. Dr. Takubo recorded petitioner's description of "a

[9] A wheal is "the typical lesion of urticaria, the dermal evidence of allergy; it is a smooth, slightly elevated, discolored area on the body surface, often accompanied by severe itching." DORLAND'S at 2080.

questionable anaphylactic type reaction" to the flu vaccine 15 years prior. Id. He also recorded petitioner's description of her reaction to the test doses of the flu vaccine as "significant shortness of breath and chest tightness" which led to the production of yellow sputum with no gross fever. Id. at 1325. Dr. Takubo continued petitioner's steroids, antibiotics, and nebulizers, and started her on a Symbicort inhaler again. Id. at 1327. Petitioner's respiratory symptoms improved and she was discharged in stable condition three days after admission, on October 15, 2013, with diagnoses of: (1) Acute exacerbation of asthma; (2) Dyspnea; (3) Reaction to flu vaccine;[10] and (4) Cough. Pet. Ex. 11 at 1211-12.

In an addendum to the records from the day of the allergy testing, Nurse Wotring wrote that she was advised on October 14, 2013, that petitioner was in the hospital with a flare-up of COPD that petitioner believed could have been caused by the allergy testing.[11] Pet. Ex. 13 at 2. Nurse Wotring charted: "[I] doubt that our prick tests could have done this. We did not give the flu shot." Id.

II. DISCUSSION

There are three issues to be resolved: (1) whether the administration of a prick percutaneous allergy test constitutes "administration of a vaccine" under the Act; (2) whether a prick percutaneous allergy test containing flu vaccine constitutes "receipt" of a vaccine under the Act; and (3) whether petitioner's prick percutaneous allergy test constitutes a "vaccine" under the Act.

Petitioner contends that she was administered a vaccine under the Act because the prick percutaneous allergy test she received involved placing a test dose of the flu vaccine itself onto her skin. Pet. Resp. at 3. Petitioner argues that content is more important than method of administration when determining whether the allergy test is a vaccine. Id. at 3-4. Respondent argues that the allergy test does not constitute a vaccine as intended in the Vaccine Act and that to find otherwise would be to broaden the scope of the Act greater than intended by Congress when it established the Vaccine Program. Mot. to Dismiss at 5-6.

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. 42 U.S.C. §300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rept. No. 99-908, 99th Cong., 2d Sess. at 3 (reprinted in 1986 U.S.C.C.A.N. at 6287, 6344)).

[10] It is unclear what Dr. Takubo meant by this diagnosis, as petitioner did not receive a flu vaccine, but the allergy test at issue.

[11] COPD is "[c]hronic obstructive pulmonary disease." DORLAND'S at 412 (32d ed. 2012).

The Vaccine Act states:

> [A]ny person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1) of this section, file a petition for compensation under the Program.

42 U.S.C. §300aa-11(b)(1)(A). To be eligible for compensation, petitioners must as a threshold matter demonstrate that they "received a vaccine as set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-11(c)(1)(A).

The Federal Circuit described the various subsections of 42 U.S.C. § 300aa-11 as "gate-keeping" provisions. Amendola v. Sec'y of Health & Human Servs., 989 F.2d 1180, 1182 (Fed. Cir. 1993). If petitioners are unable to demonstrate they received a vaccine listed on the Table, "any injury caused by its administration is not compensable, and the injured party has no cognizable claim under the Vaccine Act." Scanlon v. Sec'y of Health & Human Servs., 114 Fed. Cl. 135, 141 (2013).

B. Interpretation of the Vaccine Act

Complicating the issue at hand is that the Vaccine Act does not define the terms "administration," "received," or "vaccine." When interpreting a statute, undefined words in the statute must be given their "ordinary or natural meaning." Leocal v. Ashcroft, 543 U.S. 1, 9 (2004) (citing Smith v. United States, 508 U.S. 223, 228 (1993)). To resolve statutory ambiguity, the "starting point must be the language of the statute itself." Lewis v. United States, 445 U.S. 55, 59 (1980). Further, a court "should try to construe a statute in a way which is consistent with the intent of Congress." Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1570-71 (Fed. Cir. 1993).

The intent of Congress in creating the Act was to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."[12] 42 U.S.C. § 300aa-1. "Where the language of the statute is

[12] Other noted purposes of the Vaccine Act are to compensate vaccine-injured persons and to protect vaccine manufacturers and administrators from costly litigation. See 42 U.S.C. § 300aa-11(a)(2)(A); Bruesewitz v. Wyeth LLC, 562 U.S. 223, 226 (2011) (noting the Vaccine Act was enacted "[t]o stabilize the vaccine market and facilitate compensation"); Schafer v. American Cyanamid Co., 20 F.3d 1, 2 (1994) ("An important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufactures in the market"); see also Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373, 1378 (2015) ("Recognizing that 'a small but significant number' of individuals will be 'gravely injured' as a result of inoculation….Congress created a federal no-fault compensation scheme under which awards were to 'be made to vaccine-injured persons

unambiguous, there is no need to probe for Congressional intent, nor to 'construe' the statutory language." Webb v. Sec'y of Health & Human Servs., No. 91-373V, 1992 WL 19309, at *2 (Fed. Cl. Spec. Mstr. Jan. 17, 1992). Further, "[w]hen the legislative purpose is incorporated in a complex piece of legislation, such as those establishing a major regulatory or entitlement program, the meaning of any particular phrase or provision cannot be securely known simply by taking the words out of context and treating them as self-evident." Amendola, 989 F.2d at 1182. The Vaccine Act, as a major federal compensation program, is just such a complex piece of legislation. Id.

The Vaccine Act is a limited waiver of sovereign immunity and as such must be given a "strict and narrow construction." Leroy v. Sec'y of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2002) (quoting Holihan v. Sec'y of Health & Human Servs., 45 Fed. Cl. 201, 207 (1999)). The waiver of sovereign immunity must be strictly construed "in favor of the sovereign." Leroy, 2002 WL 31730680, at *4 (quoting United States v. Nordic Village, Inc., 503 U.S. 30, 34 (1992)) (internal citations omitted). Further, as the waiver of sovereign immunity in the Vaccine Act, 42 U.S.C. §300aa-11(b)(1)(A), the section at issue in this case, requires a narrow construction. Sigal v. Sec'y of Health & Human Servs., No. 07-489V, 2008 WL 2465790, at *4 (Fed. Cl. Spec. Mstr. May 23, 2008).

1. "Administration of a Vaccine"

The Vaccine Act provides that "any person who has sustained a vaccine-related injury….as the result of the administration of a vaccine set forth in the Vaccine Injury Table may….file a petition for compensation under the Program." 42 U.S.C. §300aa-11(b)(1)(A). As the court noted in Pannell v. Sec'y of Health & Human Servs., No. 94-658, 1995 WL 432643 (Fed. Cl. Spec. Mstr. July 7, 1995), "it is not the mere existence of the listed vaccines or their proximity to patients that gives rise to a potential claim under the Act, it is their administration." Pannell, 1995 WL 432643, at *3.

The court in Amendola held that Congress intended the Act to apply to practitioners who administered a vaccine. Amendola 989 F.2d at 1186. Based on Nurse Wotring's description of the test, she clearly intended to administer an allergy test, not to administer a vaccine. Per Nurse Wotring, she did not proceed with the intradermal testing after petitioner tested positive to the scratch test. Pet. Ex. 22 at 1.

Similarly, the court in Klahn v. Sec'y of Health & Human Servs. concluded that an "administrator" of a vaccine is limited to "one who actually inoculates the individual" and is not extended to others in the medical chain. Klahn v. Sec'y of Health & Human Servs., 31 Fed. Cl. 382, 389 (1994). As respondent noted, the prick percutaneous allergy test is a diagnostic test, and it is not performed to provide inoculation from a disease. Resp. Resp. to April 6, 2017

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quickly, easily, and with certainty and generosity.'") (citing H.R. Rep. No. 99-908, at 3, 1986 U.S.C.C.A.N. at 6344).

Order at 3.[13] "The allergy 'test' was a mere antecedent to determining whether petitioner would *subsequently* receive a flu vaccine." Id. at 6-7. Nurse Wotring therefore was not an administrator of a vaccine under the Act.

In summary, Nurse Wotring intended to administer a diagnostic allergy test to identify whether petitioner had an allergy to the flu vaccine that would prevent her from receiving the flu vaccine in the future. The allergy test was a precursor to a flu vaccination, not an actual flu vaccination itself. Therefore, Nurse Wotring did not administer a vaccine pursuant to the Act, and petitioner did not sustain an injury as the result of the administration of a vaccine. To the extent that petitioner suffered an injury, such injury was caused by allergy testing. To find otherwise would be to expand the scope of the Vaccine Act more broadly than intended by Congress.

2. "Receive"

To determine the ordinary or natural meaning of "receive," petitioner provides a dictionary definition: "to come into possession of," "to act as a receptacle or container for," or "to permit to enter."[14] Petitioner argues that when the test doses of flu vaccine were scratched or placed onto her skin, she came into possession of and acted as a receptacle for the vaccine, thus constituting receipt of the vaccine. Pet. Resp. at 3.

Petitioner also points to definitions of "receive" as defined in a line of cases previously adjudicated in the Vaccine Program determining whether children "received" vaccines *in utero* when their mothers were vaccinated while pregnant. Petitioner's Response to the Court's April 6, 2017 Order ("Pet. Resp. to April 6, 2017 Order") at 5-10 (ECF No. 25). Petitioner notes that earlier cases in the Program held that an *in utero* child could not "receive" a vaccine within the meaning of the Act if the vaccine was administered to his or her mother while pregnant.[15] Pet.

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[13] Respondent cites to *Allergy Diagnostic Testing*, WORLD ALLERGY ORGANIZATION http://www.worldallergy.org/professional/allergic_diseases_center/allergy_diagnostic/ (last visited May 23, 2018).

[14] Petitioner cites to Definition of RECEIVE, Merriam-Webster, https://www.merriam-webster.com/dictionary/receive (last visited May 23, 2018).

[15] See, e.g., Rooks v. Sec'y of Health & Human Servs., No. 93-869, 1995 WL 522769 (Fed. Cl. Spec. Mstr. Aug. 22, 1995) (finding that a child did not "receive" the MMR vaccine *in utero* when the vaccine was administered to his pregnant mother), *vacated*, No. 93-689, 2000 WL 816825 (Fed. Cl. Spec. Mstr. June 5, 2000); Melton v. Sec'y of Health & Human Servs., No. 01-105, 2002 WL 229781 (Fed. Cl. Spec. Mstr. Jan. 25, 2002) (finding that a child did not "receive" the MMR vaccine *in utero* when the vaccine was administered to her pregnant mother), *vacated*, No. 01-105, unpublished Order filed July 8, 2002). Of note, both Rooks and Melton were later vacated and the *in utero* children in both cases were found to have "received" vaccines within the meaning of the Act when they were administered to their pregnant mothers.

Resp. to April 6, 2017 Order at 6. However, petitioner also notes that in later cases the court determined that *in utero* children do in fact "receive" vaccines within the meaning of the Act, and she cites to those successful cases to determine the meaning of "receive" in the instant case.[16] Id. Congress thereafter amended the Act to include children who received vaccinations *in utero*.[17]

The court in the Castaneda *in utero* case used a similar working definition of "receive" as provided by petitioner in the instant case. Castaneda, 2012 WL 1722346, at *6 (citing Am. Heritage Dict., 1508 (3d ed. 1996) (determining "received" to mean "to take or acquire," "get," "experience," "to have inflicted or imposed," "to….intercept the impact of," or "to take in"). Petitioner argues that when the test doses of flu vaccine were scratched or placed onto her skin, she similarly "got, experienced and took in the flu vaccine." Pet. Resp. to April 6, 2017 Order at 8.

As both petitioner and respondent stipulated, a prick percutaneous allergy test like the one administered to petitioner is "a small amount of an allergen placed or pricked on the epidermal layer of the skin." Joint Stip. dated Oct. 30, 2017, at ¶ 2. The epidermis is "the outermost, nonvascular layer of the skin….varying in thickness from 0.07 to 0.12 mm."[18] Nurse Wotring explained that petitioner "only received the two prick skin tests. She did not receive [i]ntradermal skin tests nor did she receive the actual [f]lu vaccine of 0.5 ml [i]ntramuscularly." Pet. Ex. 22 at 1. The test doses were placed or scratched *onto* petitioner's epidermis. In this sense, petitioner did not "take in" or "act as a receptacle for" the flu vaccine.

The flu vaccine at issue, Fluzone, is a "[s]uspension for injection" designed by the manufacturer to be injected intramuscularly.[19] Highlights of Prescribing Information at 1-2.

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[16] See, e.g., Burch v. Sec'y of Health & Human Servs., No. 99-946, 2010 WL 1676767 (Fed. Cl. Spec. Mstr. April 9, 2010) (finding on reconsideration that an *in utero* child "received" an MMR vaccination when it was administered to her pregnant mother); Castaneda v. Sec'y of Health & Human Servs., No. 11-749, 2012 WL 1722346 (Fed. Cl. Spec. Mstr. April 24, 2012) (finding that an *in utero* child "received" the HPV vaccine when it was administered to her pregnant mother).

[17] Respondent stated that the amendment to the Act was not in response to the court's *in utero* case decisions, but rather because "Section 3093(c) of the 21st Century Act….expanded the [Vaccine Program's] coverage to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and subject to an excise tax." Resp. Resp. to April 6, 2017 Order at 9 (citing Frequently Asked Questions, Health Resources & Services Administration, https://www.hrsa.gov/vaccine-compensation/faq/index.html (last visited May 23, 2018)).

[18] DORLAND'S at 630.

[19] Not all vaccines are injected intramuscularly. However, the manufacturer specifies that Fluzone is a suspension for injection to be injected intramuscularly.

There is no language in the Act or the regulations referencing a prick percutaneous allergy test as a condition covered within the Table. Therefore, petitioner did not "receive" the flu vaccine under the Vaccine Act because she was exposed to only a minute amount upon the outermost layer of her skin.

3. "Vaccine"

Although the Vaccine Act does not define "vaccine," the term is defined in 26 U.S.C. § 4132(a)(2)[20] as "any substance designed to be administered to a human being for the prevention of 1 or more diseases." 26 U.S.C. § 4132 (2013). Similarly, Dorland's Illustrated Medical Dictionary defines "vaccine" as "a suspension of attenuated or killed microorganisms….or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases."[21] The Department of Health and Human Services, as the agency charged by Congress to administer the Vaccine Injury Compensation Program, defines "vaccine" on its website as "[a] product that produces immunity therefore protecting the body from the disease. Vaccines are administered through needle injections, by mouth and by aerosol."[22] Further, the website defines "vaccination" as an "[i]njection of a killed or weakened infectious organism in order to prevent the disease."[23] These definitions all incorporate the purpose of a vaccine – to immunize and protect from disease. Thus, the ordinary or natural meaning of "vaccine" cannot be separated from its purpose to immunize.

As respondent notes, the purpose of petitioner's allergy test was to diagnose an allergy. Resp. Resp. to April 6, 2017 Order at 6-7. Nurse Wotring stated unequivocally that she "did not give the flu shot." Pet. Ex. 13 at 2. This statement supports respondent's position that the allergy test did not constitute a vaccine. As previously noted, one full dose of Fluzone for injection in patients age nine and older is 0.5 ml, but according to Nurse Wotring, petitioner was exposed to "far less" than even 0.02-0.05 ml. Pet. Ex. 22 at 1; Highlights of Prescribing Information at 1. The minute amount of Fluzone was not administered for the purpose of providing immunization to a disease. Instead, it was given as part of a diagnostic allergy test to determine whether petitioner could safely receive the flu vaccine.

In summary, the evidence shows that petitioner underwent an allergy test to determine whether she could safely receive a vaccine. The testing revealed that petitioner tested positive and thus the flu vaccine was not administered. The undersigned agrees with Nurse Wotring that

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[20] 26 U.S.C. § 4132 includes definitions of terms relating to 26 U.S.C. § 4131, the section of the Internal Revenue Code that imposes an excise tax on taxable vaccines.

[21] DORLAND'S at 412.

[22] Glossary, vaccines.gov, https://www.vaccines.gov/resources/glossary/index.html (last visited May 23, 2018).

[23] Id.

under these specific facts and circumstances, a flu vaccine was not administered.

C. The Court Cannot Expand the Scope of the Vaccine Act

Moreover, the undersigned does not have the authority to amend the Act by expanding it to include allergy testing. The addition of vaccines to the Table may occur only through the process described in 42 U.S.C. § 300aa-14(c). As previously noted, Congress may amend the Act as needed and has done so in the past.

> To include a diagnostic procedure, such as prick percutaneous allergy testing, would require similar congressional action or the agency rulemaking process. The expansion of Vaccine Act coverage to include diagnostic testing is a matter of policy, the proper theater of which is the "halls of Congress." Brausewetter v. Sec'y of Health & Human Servs., No. 99-278V, 1999 WL 562700, at *4 (Fed. Cl. Spec. Mstr. Jul. 16, 1999) (citing Keene Corp. v. United States, 508 U.S. 200, 217 (1993). "The court enjoys 'no liberty to add an exception … [or] to remove apparent hardship.'" Id. at 217-218.

III. CONCLUSION

For all of the reasons discussed above, the undersigned finds that petitioner did not receive a vaccine under the Vaccine Act and is therefore not entitled to compensation in the Vaccine Program. Accordingly, respondent's Motion to Dismiss is **GRANTED** and petitioner's petition is **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court shall enter judgment in accordance herewith.[24]

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[24] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.